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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,115	08/31/2005	Martin Hendrix	01-2112	5580
28519 7590 03/25/2010 MICHAEL P. MORRIS BOEHRINGER INGELHEIM USA CORPORATION 900 RIDGEBURY RD P O BOX 368 RIDGEFIELD, CT 06877-0368				
			EXAMINER MURRAY, JEFFREY H	
			ART UNIT 1624	PAPER NUMBER
			NOTIFICATION DATE 03/25/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

### Office Action Summary

**Application No.**

10/525,115

**Applicant(s)**

HENDRIX ET AL

**Examiner**

JEFFREY H. MURRAY

**Art Unit**

1624

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-9, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 8 and 14 is/are rejected.
- 7) ☒ Claim(s) 1-5, 7, 9 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1-5, 7-9, 13 and 14 are pending in this application. Claims 6 and 10-12 have been cancelled. This action is in response to the applicants' amendment filed on December 23, 2009.

### ***Withdrawn Rejections/Objections***

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

Claim 8 and 14 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Treating an impairment of learning and/or memory is not enabled.

Applicants have argued that there is a nexus between the testing they have performed in the specification and a use in carrying out the claimed methods. They point specifically to a document Van der Staay, Neuropharmacology, vol. 55, pp. 908-918 (2008) to strengthen their belief that there is a nexus. Unfortunately, the specification of an application must be enabling as of the filing date (see MPEP 2164.05(a)) thus any published documents supporting the concept of enablement must be dated on or before the filing date of the current application. Here, the Van der Staay

document is accepted on July 4, 2008, while the application was filed back in 2005, thus the document, as well as the arguments used by the applicants referencing this document, can not be used to assist in teaching enablement of the current invention. This argument also holds true for other documents and references used to show enablement within the applicants' arguments such as Reymann et. al. (2007); Wunder et. al. (2005); and Lugnier, et. al. (2006).

Contrary to the applicants' assertion on page 11 as to "providing no evidence to support why it doubts the truth or accuracy of the inventor's statements..." The examiner has provided documentation and discussed the aspects of the claims at length in a previous rejection. The suggestion that examiner has provided no evidence is perplexing and not well taken.

The examiner has pointed to specific types of diseases and disorders related to memory and learning impairment and how some are untreatable. (See "post traumatic amnesia" in the previous Wikipedia reference"). The references involved discuss not general statements, but rather specific diseases and disorders that are directly related to a memory or learning disorder which speaks directly to the claim elements themselves. Applicants argue on page 13 of the remarks section that "while a complete cure for Alzheimer's remains elusive, there are treatments available which slow or lessen the effects of the condition and/or prevent worsening of the condition. While a statement like this may have some truth, the rejected claims are not directed towards "a method of treating Alzheimer's disease" but rather they are directed towards the general

treatment of memory and/or learning impairment. The rejection of claims 8 and 14 is maintained. No new matter permitted. Appropriate correction is required.

***Allowable Subject Matter***

Claims 1-5, 7, 9 and 13 are allowed.

Claims 1-5, 7, 9 and 13 are free of the prior art. The closest prior art to the claims is Miyashita, et. al., Heterocycles (1990), 31(7), 1309-14. Miyashita, et. al. however, teaches a phenyl ring in the R<sup>2</sup> position, not a cycloalkyl group, and also teaches an unsubstituted phenyl ring for R<sup>1</sup>.

***Conclusion***

Claims 8 and 14 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/  
Patent Examiner , Art Unit 1624

/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624

Application/Control Number: 10/525,115  
Art Unit: 1624

Page 6